REMARKS

I. Restriction Requirement

The Requirement alleges that the pending claims are directed to three distinct inventions under 35 U.S.C. § 121, apparently set forth as follows:

Group I: Claims 1-19, 42-43, said to be drawn to a kit comprising at least one targeting-therapeutic construct and the composition thereof, classified in class 424, subclass 139.1 or 178.1+;

Group II: Claims 20-23, 33-37, said to be drawn to an imaging kit, classified in class 424, subclass 9.1+; and

Group III: Claims 24-32, 38-41, said to be drawn to a kit for treatment of cancer having a second therapeutic or targeting agent, classified in class 424, subclass 1.49+ or class 514, subclass 2.

The inventions of Groups I, II and III are said to be distinct because they are allegedly "drawn to kits for different utility which require different materials, steps and modes of action, thus they are distinct products. For example kits that may be used for treatment of cancer may or may not comprise detectable imaging agents" (Requirement at Item 2).

II. Summary of Traversal

The Restriction Requirement contains errors of such magnitude that Applicants are compelled to traverse. In summary, the Requirement ignores essential claimed features, notably within claim 1; ignores proper linking claims, particularly claims 1, 32 and 43; fails to properly show that the inventions are "distinct"; overlooks proper procedure even if the inventions were distinct; and classifies all groups within the same class of invention (424).

Applicants therefore traverse the Restriction Requirement on the basis that it is inconsistent with many grounds of long-established U.S. Restriction practice.

III. Detailed Traversal

The Group I invention, represented by claims 1-19, 42 and 43, is said to be drawn to "a kit comprising at least one targeting-therapeutic construct and the composition thereof" (Requirement at Item 2).

In contrast, claim 1, believed to be most representative, is in fact drawn to a kit comprising at least one targeting agent-therapeutic agent construct that binds to an aminophospholipid in combination with either a targeting agent-detectable agent construct or at least a second anti-cancer agent. Independent claim 43 is drawn to a kit comprising the aminophospholipid-binding, targeting agent-therapeutic agent construct in combination with the targeting agent-detectable agent construct and the second anti-cancer agent. Independent claim 42 is drawn to a kit comprising the aminophospholipid-binding, targeting agent-therapeutic agent construct in combination with only the second anti-cancer agent.

The essential feature of the claims has thus been ignored, namely that the aminophospholipid-targeted therapeutic agent *must be* combined with at least one other component (the targeting agent-detectable agent construct and/or the second anti-cancer agent). There is no claim within the Group I invention that requires only the aminophospholipid-binding, targeting agent-therapeutic agent construct. The Restriction Requirement is thus fundamentally flawed, as it is based upon a mischaracterization of claim 1.

Properly defining claim 1 as requiring the recited targeting agent-therapeutic agent construct in combination with either a targeting agent-detectable agent construct and/or a second anti-cancer agent entirely removes the basis for restriction. Simply put, the claims of alleged Group I cannot stand alone, but require an element from either Group II or Group III to satisfy the claimed features.

Claim 1 is therefore a linking claim, which properly joins the imaging and combined cancer treatment aspects of the overall invention. Rather than being separate groups of invention, the targeting agent-detectable agent constructs and the second anti-cancer agents are, at best, separate species within a proper generic invention. As species, and as proper dependent claims, each of claims 20-23 and claims 24-31 must be maintained in the case.

Several other lines of evidence compel a finding of unity of invention. First, dependent claim 32 and independent claim 43 each clearly recite all three claimed elements (the aminophospholipid-targeted therapeutic agent, the targeting agent-detectable agent construct and the second anti-cancer agent). Following the alleged restriction would place claim 32 in Group III, said to be drawn to aminophospholipid-targeted therapeutic agents in combination with only second anti-cancer agents; and would place claim 43 in Group I, apparently drawn to aminophospholipid-targeted therapeutic agents alone. Only unifying all three groups of invention allows claims 32 and 43 to be properly examined.

Second, the Office has not provided reasoning adequate to show that the inventions of Groups I through III are in fact properly restrictable or distinct. MPEP 806.05(c) states that a requirement for restriction must be supported by "both two-way distinctness and reasons for insisting on restriction", such as separate classification, status or field of search, separate particulars of patentability or combinations with distinct utility. MPEP 806.05(c) at page 800-34, column 1. In contrast, the present Requirement states only that "kits that may be used for treatment of cancer may or may not comprise detectable imaging agents" (Requirement at Item 2, emphasis added). The "may or may not" standard does not even approach the two-way distinctness required for insisting on restriction.

Third, even presuming that the Office refuses to categorize Groups II and II as species within a generic invention, and maintains that they are distinct inventions, the distinct inventions must be maintained in the same case with proper linking claims. MPEP 809 clearly states that, even with distinct inventions, "the linking claims must be examined with the invention elected, and should any linking claim be allowed, the restriction requirement must be withdrawn." Any claims to non-elected inventions, even if previously canceled, must then be reinstated in the case. MPEP 809 at page 800-39, column 2. As claims 1 and 43 are proper linking claims, each of claims 33-37 and claims 38-42, even if drawn to distinct inventions, which is contested, must be maintained in the case.

Fourth, and very compelling, given the many unifying features of the invention described above, it is not surprising that all three allegedly distinct inventions are in fact classified in the same group of invention (class 424). This contradicts the Requirement at Item 3, which alleges that the inventions have received a different classification. Searching only in class 424 also shows that there would be no undue burden on the Examiner should all claims be examined together. In addition to contravening MPEP 806.05(c), which requires a "separate classification", the Requirement therefore falls foul of MPEP 803, which requires a "serious burden" on the examiner should restriction not be made. "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." MPEP 803 at page 800-3, column 2.

Accordingly, Applicants respectfully traverse the Restriction Requirement and request that it be withdrawn. Applicants intend to Petition should the Requirement be maintained.

IV. Provisional Election

Despite Applicants traversal and intent to petition, Applicants provisionally elect the Group I invention for examination. It is noted that this provisional election includes claim 43, which requires the presence of an aminophospholipid-targeted therapeutic agent, a targeting agent-detectable agent construct and a second anti-cancer agent.

V. Species Election Requirement and Response

The Requirement also states that the claims are directed to various patentably distinct species, and recites the existence of "various targeting agents, various antibodies, various therapeutic agents" (Requirement at Item 4). However, the requirement to elect a species for initial prosecution is only made with respect to the Group II invention.

Should the Office have intended the species election requirement to apply to all groups of invention, or to the single unified invention defined after considering the present paper, Applicants respectfully request further clarification of the perceived "various" species. MPEP 809.02(a) requires the Office to "clearly identify" each, or at least exemplary, disclosed species. In the absence of such information, Applicants cannot assume the responsibility for electing further species and therefore respectfully request that the "various" claimed patentably distinct targeting agents, antibodies and therapeutic agents be identified so that an informed election of species can be made.

Currently only the detectable agent species are set forth with sufficient detail to allow an election. Despite the fact that the species of detectable agent apply only to the Group II invention and Applicants have provisionally elected the Group I invention, in the belief that all claims define a single, unified invention and in order to progress the case to examination in good faith, Applicants currently elect nuclear magnetic isotopes as the species to begin examination.

VI. Status of the Claims

Claims 1-43 remain pending in the case. Claim 23 reads directly on the elected species of detectable agent. Claims 21 and 22 do not read on the elected species of detectable agent.

VII. Conclusion

No fees should be due in connection with the present paper. However, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Assistant Commissioner is hereby authorized to deduct said fees from Williams, Morgan & Amerson, P.C., Deposit Account No. 50-0786/4001.002383.

In conclusion, Applicants submit that the present claims define a unified invention and respectfully request that the Restriction Requirement be withdrawn. Should Examiner Sharareh have any questions or comments, a telephone call to the undersigned Applicant's representative is earnestly solicited.

Respectfully submitted,

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